

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of: Asgeir Saebo *et al.*
Serial No.: 09/544,004
Filed: 04/06/2000
Entitled: CONJUGATED LINOLEIC ACID COMPOSITIONS

Group No.: 1617
Examiner: S. Wang

APPELLANTS' REPLY BRIEF
APPEAL NO.:

Mail Stop Appeal Brief - Patents
Commissioner for Patents and Trademarks
P.O. Box 1450
Alexandria, VA 22313-1450

CERTIFICATE OF MAILING UNDER 37 C.F.R. § 1.8(a)(1)(i)(A)	
I hereby certify that this correspondence (along with any referred to as being attached or enclosed) is, on the date shown below, being deposited with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to: Mail Stop Appeal Brief - Patents, Commissioner for Patents and Trademarks P.O. Box 1450 Alexandria, VA 22313-1450	
Dated: <u>August 30, 2006</u>	By: <u>Mary Ellen Waite</u> Mary Ellen Waite

Sir:

This Brief is in reply to the Examiner's Answer mailed June 30, 2006.

It is not believed that any fees are necessary for this reply. However, if any fees are necessary, the Examiner is hereby authorized to charge Deposit Account No. 08-1290 the fee associated with this Reply Brief and any other fees associated with this communication. Please reference Attorney Docket No.: CONLINCO-04284 when charging the Attorney Deposit Account. A request for oral examination is being filed concurrently herewith.

This Brief is transmitted in triplicate. [37 C.F.R. § 1.192(a)].

ARGUMENT

The Office's acceptance of the statements of the real party in interest, status of claims, status of amendments after final, summary of invention, and issues, and grouping of the claims is appreciated.

Below, Appellants specifically address the following issues from the initial Appeal Brief:

Issue 1 – Whether Claims 1-5, 10-19, 24-30 and 39 are obvious over both Cook et al. (U.S. Pat. No. 5,760,082) and Lievense (U.S. Patent No. 6,159,525) in view of Cain et al. (WO 97/18320), Remmereit (U.S. Patent No. 6,034,132) and Appellant's Disclosure.

Issue 2 – Whether Claims 10-19 and 24-34 are unpatentable under the judicially created doctrine of obviousness-type double patenting over claims 2, 3 and 8-22 of Fimreite (U.S. Patent No. 6,524,527).

Issue 1 – Whether Claims 1-5, 10-19, 24-30 And 39 Are Obvious Under 35 U.S.C. §103(a)

1. The Examiner Has Not Established A *Prima Facie* Case Of Obviousness

In its Appeal Brief, Applicant argued that the Examiner has not established a *prima facie* case obviousness because the Examiner admits that the Cook, Lievense, Cain and Remmereit references fail to teach compositions, food products, or food supplements comprising an isomerized conjugated linoleic acid moiety, at least one free radical scavenger, and at least one metal chelator: “The primary references do not teach expressly the employment of a combination of antioxidant and metal (oxidant) chelator, such as ascorbic acid and lecithin, or the use of a commercial antioxidant product, Controx, or particularly point out the amount of VOC.” Office Action dated June 29, 2005, page 3 (Paper No. 26). The Examiner has maintained this admission in the Examiner's Answer. Answer at p.5

In response to the Applicant's arguments, the Examiner states that "appellants misread "teach or suggest" as teach only, which is not a proper standard of establishing a prima facie of obviousness. . . . As discussed in the rejections the employment of two well-known antioxidants in CLA composition would have been obvious to one of ordinary skill in the art." Answer at p.7.

Applicant's respectfully disagree. As established in the Saebo Declaration (attached to Applicants Appeal Brief), the inventors found that the teachings of the prior art **were not sufficient** to stabilize Conjugated Linoleic Acid (CLA). The Examiner has not disputed or otherwise disproved this data-supported fact. As a result, if the cited references erroneously teach that a single antioxidant can be used to stabilize CLA, why would one of skill in the art be motivated to use a separate antioxidant and a separate metal chelator to stabilize CLA? In effect, the cited references teach away from the claimed invention and thus cannot be combined to make a prima facie case of obviousness. This is only one reason why the claimed invention is not obvious and why the Examiner's framing of the issue as being whether "concomitantly employing compounds, old and well known for the same use is obvious to the skilled artisan" is misguided. Answer at 8.

Moreover, since the Examiner has raised the "teach or suggest" issue, Applicants respectfully submit that there is no motivation to combine or modify the cited references to teach the present invention. A recent Federal Circuit case explicitly discusses the standards for establishing motivation to combine. (*See, In re Lee*, 277 F.3d 1338 (Fed. Cir. 2002)).

Specifically, the Federal Circuit held that:

The factual inquiry whether to combine references must be thorough and searching. It must be based on **objective evidence** of record. **This precedent has been reinforced in myriad decisions, and cannot be dispensed with.**¹

¹ *See, In re Lee*, 277 F.3d 1338, 1344 (Fed. Cir. 2002); internal citations omitted; emphasis added.

Furthermore, an Examiner may not simply rely on conclusory statements even for what they think might be common sense or well known in the art:

The 'common knowledge and common sense' on which the Board relied in rejecting Lee's application are not the specialized knowledge and expertise contemplated by the Administrative Procedure Act. Conclusory statements such as those here provided do not fulfill the agency's obligation. This court explained in *Zurko*, 258 F.3d at 1385, 59 USPQ2d at 1697 that 'deficiencies of the cited references cannot be remedied by the Board's general conclusions about what is 'basic knowledge' or 'common sense.' The Board's findings must extend to all material facts and must be documented on record, lest the 'haze of so-called expertise' acquire insulation from accountability. 'Common knowledge and common sense,' even if assumed to derive from the agency's expertise, do not substitute for authority when the law requires authority.²

In the instant case, the only objective evidence of record as provided in the Saebo Declaration is that the teachings of the prior art do not describe how to adequately stabilize CLA. Again, the Examiner has not refuted or rebutted this evidence. Instead, the Examiner makes the sole argument that those skilled in the art would be motivated to use the claimed components to obtain the claimed results because the “designated components were old, of known character.” This is in effect a “common knowledge and common sense” analysis that has been discredited by the Federal Circuit. The references themselves need to either identify the problem (as discussed in more detail below) or teach or suggest the desirability of using separate metal chelators and antioxidants to stabilize CLA. There is no objective evidence providing such teaching. All that is provided is the conclusory statements of the Examiner. There is no “strong” *prima facie* case of obviousness as suggested by the Examiner. Answer at 7.

2. The Claimed Invention Also Lies In The Discovery Of The Source Of A Problem Unrecognized In The Prior Art

As argued in the Applicant's Appeal Brief, the Examiner has failed to consider the claimed invention in light of the fact that it lies in the discovery of the source of a problem

² *Id.* at 1344-1345.

unrecognized in the prior art. It is a well-established rule in patent law that "[i]t should not be necessary . . . to point out that a patentable invention may lie in the discovery of the source of a problem even though the remedy may be obvious once the source of the problem is identified." (*In re Sponnable*, 405 F.2d 578, 585 (C.C.P.A. 1969); *In re Kosei Nomiya et al.*, 509 F.2d 566, 571 (C.C.P.A. 1975)).

The Examiner has failed to address this argument in the Answer. As such Applicant's are entitled to issuance of the claims.

Instead of addressing this argument, the Examiner has continued to focus on whether the Saebo Declaration contains evidence of unexpected results. In fact, the Saebo Declaration both contains evidence of unexpected results and shows that the Applicant identified a previously unknown problem in the stabilization of CLA.

With respect to the unidentified problem, the Saebo Declaration contains data demonstrating that prior art compounds such as ascorbic acid are insufficient to stabilize CLA and that a combination of antioxidants and chelators is required. This is in contrast to the prior art which taught that only a single antioxidant is required. As established in the Declaration, prior art CLA compositions contained "large amounts of volatiles compared to oils normally used in food production." Saebo Declaration, ¶5. Thus, those of skill in the art did not know how to properly stabilize CLA or that at least antioxidant and at least one metal chelator were required. Moreover, the references cited by the Examiner provide no evidence that this problem was recognized. Applicants recognized that the source of this problem was CLA's susceptibility to breakdown in the presence of metal ions. (Specification, page 24, lines 20-25). This "source of the problem" had gone unrecognized in the prior art. Thus, it is no surprise that the prior art did not teach the combination of the claimed ingredients.

With respect to unexpected results, the Examiner own admissions confirm exactly why the results are unexpected. The Examiner states: "Further, the data can not explain why use ascorbic acid alone would not [be] effective, considering that ascorbic acid may function both as metal chelator and antioxidant." Answer at 9. Applicant respectfully submits that the data does not have to explain anything – the data is a fact that remains unrebutted by the Examiner. Moreover, this is exactly why it is unexpected that separate antioxidants and metal chelators are required to stabilize CLA when the expectation of the prior art was that a compound such as ascorbic acid alone was sufficient. This highlights why the Examiner has not rebutted or provided objective evidence to overcome the Saebo declaration.

The MPEP requires that:

Office personnel should consider all rebuttal arguments and evidence presented by applicants. . . . *In re Beattie*, 974 F.2d 1309, 1313, 24 USPQ2d 1040, 1042-43 (Fed. Cir. 1992). . . . **Office personnel should avoid giving evidence no weight**, except in rare circumstances. *Id.* See also *In re Alton*, 76 F.3d 1168, 1174-75, 37 USPQ2d 1578, 1582-83 (Fed. Cir. 1996).

* * *

A determination under 35 U.S.C. 103 should rest on **all the evidence** and should not be influenced by any earlier conclusion. See, e.g., *Piasecki*, 745 F.2d at 1472-73, 223 USPQ at 788; *In re Eli Lilly & Co.*, 902 F.2d 943, 945, 14 USPQ2d 1741, 1743 (Fed. Cir. 1990). Thus, once the applicant has presented rebuttal evidence, Office personnel should **reconsider** any initial obviousness determination in view of the entire record. See, e.g., *Piasecki*, 745 F.2d at 1472, 223 USPQ at 788; *Eli Lilly*, 902 F.2d at 945, 14 USPQ2d at 1743.³

Additionally, the Courts have held as follows:

When *prima facie* obviousness is established and evidence is submitted in rebuttal, the decision-maker must start over An earlier decision should not . . . be considered as set in concrete, and applicant's rebuttal evidence then be evaluated only its knockdown ability. Analytical fixation on an earlier decision can tend to provide the decision with an undeservedly broadened umbrella effect. *Prima facie* obviousness is a legal conclusion, not a fact. Facts established by rebuttal evidence must be evaluated along with the facts on which the earlier conclusion was reached, not against the conclusion itself. Though the tribunal must begin anew, a final finding of obviousness may of course be reached,

³

MPEP §§2144.08; emphasis added).

but such finding will rest upon evaluation of all facts in evidence, uninfluenced by any earlier conclusion reached . . . upon a different record.⁴

The Examiner has not established a prima facie case of obvious and cannot in light of the the cited references and objective evidence provided in the Saebo Declaration.

Issue 2 – Whether Claims 10-19 and 24-34 are unpatentable under the judicially created doctrine of obviousness-type double patenting over claims 2, 3 and 8-22 of Fimreite (U.S. Patent No. 6,524,527).

The Appellant will submit a terminal disclaimer to overcome this rejection upon resolution of the §103(a) rejection (Issue 1).

CONCLUSION

For the foregoing reasons, it is submitted that the Office's rejection of Claims 1-5, 10-19, 24-30, and 39 was erroneous, and reversal of the rejection is respectfully requested. Appellant requests either that the Board render a decision as to the allowability of the claims, or alternatively, that the application be remanded for reconsideration by the Office.

Dated: March 14, 2006

J. Mitchell Jones
Registration No. 44,174

MEDLEN & CARROLL, LLP
101 Howard St., Ste. 350
San Francisco, CA 94105
608/218-6900

⁴ *In re Rinehart*, 531 F.2d 1048, 1052, 189 USPQ 143, 147 (CCPA 1976).

but such finding will rest upon evaluation of all facts in evidence, uninfluenced by any earlier conclusion reached . . . upon a different record.⁴

The Examiner has not established a prima facie case of obvious and cannot in light of the the cited references and objective evidence provided in the Saebo Declaration.

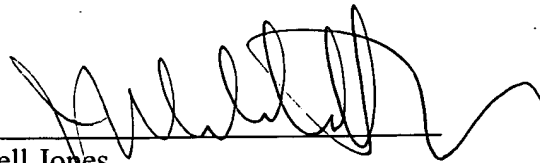
Issue 2 – Whether Claims 10-19 and 24-34 are unpatentable under the judicially created doctrine of obviousness-type double patenting over claims 2, 3 and 8-22 of Fimreite (U.S. Patent No. 6,524,527).

The Appellant will submit a terminal disclaimer to overcome this rejection upon resolution of the §103(a) rejection (Issue 1).

CONCLUSION

For the foregoing reasons, it is submitted that the Office's rejection of Claims 1-5, 10-19, 24-30, and 39 was erroneous, and reversal of the rejection is respectfully requested. Appellant requests either that the Board render a decision as to the allowability of the claims, or alternatively, that the application be remanded for reconsideration by the Office.

Dated: August 30, 2006



J. Mitchell Jones
Registration No. 44,174

MEDLEN & CARROLL, LLP
101 Howard St., Ste. 350
San Francisco, CA 94105
608/218-6900

⁴ *In re Rinehart*, 531 F.2d 1048, 1052, 189 USPQ 143, 147 (CCPA 1976).